

Attorney Docket No.: PTQ-0058
Inventors: Van Eyk et al.
Serial No.: 10/824,027
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REMARKS

Claims 1-20 are pending in the instant application. Claims 3-12 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this response. Claims 1, 2 and 13-20 have been rejected. Claims 1 and 14 have been amended. Claim 2 has been canceled in light of the amendments to claim 1. Support for these amendments is provided in the specification at page 1, lines 12-13, page 14, lines 8-16 and page 25, lines 27 through page 26, line 11 and in claim 2. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed January 11, 2005. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice nonelected claims 3-12. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

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II. Objection to Specification

In accordance with the Examiner's suggestion, Applicants have corrected the inadvertent typographical error at page 4, line 38. Specifically, the term "cased" has been replaced with the term --caused--. Withdrawal of this objection is respectfully requested.

III. Objection to Claims

Claim 2 has been objected to for the abbreviations OxPhos and TCA. Claim 2 has been canceled and claim 1 has been amended to include the subject matter of claim 2. In accordance with the Examiner's suggestion with respect to claim 2 and teachings at page 1, lines 12-13 of the specification, in amendment of claim 1, Applicants have spelled out the abbreviations at their first occurrence in the claims. Withdrawal of this objection is therefore respectfully requested.

IV. Obviousness-type Double Patenting Rejection

Claims 1, 2, 13-16, 19 and 20 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 4 of copending Application No. 10/189,820. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants are filing a terminal disclaimer

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with the requisite fee herewith. Withdrawal of this obviousness-type double patenting rejection is therefore respectfully requested.

V. Rejection of Claims under 35 U.S.C. 112, second paragraph

Claims 1, 2 and 13-20 have been rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular the Examiner suggests that claim 1 is incomplete for omitting essential steps. The Examiner suggests that the method of assessing the ability of the agent or event to modulate a preconditioning protein in a cell, tissue or organ has been omitted.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to clarify that the ability of the agent or event to modulate a preconditioning protein is assessed by detecting a modulation in the preconditioning protein in the presence of the agent or event as compared to the preconditioning protein in the absence of the agent or event. Support for this amendment can be found throughout the specification and

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in particular at page 14, lines 8-16 and page 25, lines 27 through page 26, line 11.

The Examiner also suggests that the phrase "the protein complex" in claim 14 lacks antecedent basis.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 14 as suggested by the Examiner to state --a protein complex--.

Withdrawal of these rejections under 35 U.S.C. 112, second paragraph is respectfully requested.

VI. Rejection of Claims under 35 U.S.C. 102(b)

Claims 1, 13 and 14 have been rejected under 35 U.S.C. 102(b) as being anticipated by Mochly-Rosen (U.S. Patent 6,165,977). The Examiner suggests that Mochly-Rosen discloses a method of reducing ischemic injury to a cell exposed to hypoxic conditions.

To anticipate a claim, a reference must teach every element of the claim. MPEP 2131.

As discussed in Section III, supra, claim 1 has been amended to include the subject matter of claim 2 and thus now states that the preconditioning protein is a protein of an oxidative phosphorylation (OxPhos) pathway, tricarboxylic acid (TCA) cycle, a Ca^{2+} handling protein, a chaperone protein, or a protein selected from aldehyde dehydrogenase,

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NG-dimethylarginine dimethylaminohydrolase (DDAH) and the RNA binding protein regulatory subunit DJ-1.

Mochly-Rosen does not teach a method for identifying an agent or event capable of priming a cell for preconditioning and/or inducing preconditioning based upon any of these preconditioning proteins.

Accordingly, since this reference does not teach all the elements of the claims as amended, it cannot anticipate the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. 102(b) is therefore respectfully requested.

VII. Rejection of Claims under 35 U.S.C. 102(e)

Claims 1, 2, 13, 14, 15, 16, 19 and 20 have been rejected under 35 U.S.C. 102(e) as being anticipated by Van Eyk et al. (US 2003/0022220 A1).

As acknowledged by the Examiner, this published patent application has common inventors with the instant application. Specifically, both inventors of published patent application US 2003/0022220 A1, Dr. Jennifer Van Eyk and Dr. David Kent Arrell, are also co-inventors with Dr. Steven Elliot of the instant application. Since Dr. Van Eyk and Dr. Arrell are the only two co-inventors of US 2003/0022220 A1, any invention disclosed but not claimed in

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US 2003/0022220 A1 was derived from their work. Applicants are submitting herewith a Declaration by Dr. Van Eyk and Dr. Arrell attesting to this fact.

Accordingly, teachings of US 2003/0022220 A1 are not "by another" and therefore this reference cannot be cited under 35 U.S.C. 102(e).

Withdrawal of this rejection under 35 U.S.C. 102(e) is therefore respectfully requested.

VIII. Rejection of Claims under 35 U.S.C. 103(a)

Claims 1, 13, 14, 15 and 20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (J. Mol. Cell Cardiol. 33:2037-2046 (2001)). The Examiner suggests that it would have been obvious to the person having ordinary skill in the art to identify an agent that mimics the preconditioning effects of diazoxide by designing an assay that screens for activators of the PKC- δ signaling pathway because Wang et al. teach the opening of mitochondrial K_{ATP} channels by nitric oxide to be an end effector of cardioprotection during the "second window" of preconditioning and that nitric oxide results from diazoxide induced preconditioning, which leads to activation of NF κ B via the PKC- δ signaling pathway.

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In accordance with MPEP § 2143, to render an invention *prima facie* obvious, three basic criteria must be met.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. The cited combination of prior art fails to meet these criteria with respect to the instant invention.

As discussed in Sections III and V, *supra*, claim 1 has been amended to include the subject matter of claim 2 and thus now states that the preconditioning protein is a protein of an oxidative phosphorylation (OxPhos) pathway, tricarboxylic acid (TCA) cycle, a Ca^{2+} handling protein, a chaperone protein, or a protein selected from aldehyde dehydrogenase, NG-dimethylarginine dimethylaminohydrolase (DDAH) and the RNA binding protein regulatory subunit DJ-1.

Wang et al. does not teach or suggest a method for identifying an agent or event capable of priming a cell for preconditioning and/or inducing preconditioning based upon any of these preconditioning proteins.

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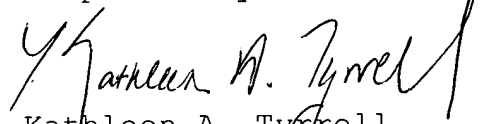
Accordingly, this reference fails to provide the requisite suggestion or motivation to one of ordinary skill in the art to modify the reference, any reasonable expectation of success, or any teaching or suggestion of all the limitations of the claims as amended.

Withdrawal of this rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

IX. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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